K030891

MAY 2 3 2003

510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: Mansour Consulting LLC
2-Address: 1308 Morningside Park Dr
Alpharetta, GA 30022 USA
3-Phone: (678) 908- 8180
4-Fax: (425) 795- 9341
5-Contact Person: Jay Mansour

6-Date summary prepared: March 18th, 2003

7-Device Trade or Proprietary Name: ULTRAEKOGEL™

8-Device Common or usual name: ULTRASOUND GEL

9-Device Classification Name: SYSTEM, IMAGING, PULSED ECHO, ULTRASONIC- GEL

10-Substantial Equivalency is claimed against the following device:

- AQUASONIC 100 from Parker Laboratories, Inc.
  510k # K802146

11-Description of the Device:

ULTRAEKOGEL™ is an electroconductive gel media used with ultrasonic pulsed echo imaging system. The gel –once applied on the defined area of the body- facilitates the intended use of the system, which is intended to project a pulsed sound beam into body tissue to determine the depth or location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver. It is supplied in 250 grams and 5 Kilograms containers with a 3-year shelf life.

12-Intended use of the device: (refer to FDA form attached)

ULTRAEKOGEL™ is an electroconductive gel media used with ultrasonic pulsed echo imaging system. The gel –once applied on the defined area of the body- facilitates the intended use of the system, which is intended to project a pulsed sound beam into body tissue to determine the depth or location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver.

13-Safety and Effectiveness of the device:

This device is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **IDENTICAL** to the predicate device. Refer to the explanations within the main submission.

FDA file reference number	510k # K802146
Attachments inside notification submission file	510k summary print out
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Identical
Materials	Identical
Performance	Identical
Sterility	Identical
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Identical
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Identical
Thermal safety	Identical
Radiation safety	Identical

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2003

INMED, LTDA
% Mr. Jay Mansour
President
Mansour Consulting, LLC
1308 Morningside Park Dr.
ALPHARETTA GA 30022

Re: K030889
Trade/Device Name: ULTRAEKOGEL™
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 MUI
Dated: March 18, 2003
Received: March 21, 2003

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K030889

510(k) Number (if known): K030889

Device Name: ULTRAEKOGEL ™

Indications for Use:

ULTRAEKOGEL™ is an electroconductive gel media used with ultrasonic pulsed echo imaging system. The gel –once applied on the defined area of the body- facilitates the intended use of the system, which is intended to project a pulsed sound beam into body tissue to determine the depth or location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver.

David R. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030889

Prescription Use ✓

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

(Optional Format 3-10-98)